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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,112	04/17/2004	Reuben Matalon	P71641US0	9858

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

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07/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,112	MATALON, REUBEN	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57,59 and 61-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57, 59, 61-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 21, 2010 has been entered.

Applicants' arguments, filed May 21, 2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 57, 59, 61-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wachtel et al. (DE 4037447 A1, translation provided previously), already of record, for the reasons set forth at pages 3-9 of the previous office action dated February 23, 2010 and pages 6-13 of the office action dated April 15, 2009, pages 3-6 of the office action dated October 15, 2007, and pages 3-5 of the office action dated August 1, 2008, of which reasons are herein incorporated by reference.

Applicant has amended claims 57, 59, and 69 to reduce the amount of lysine being claimed from 5-200mg to 5-30mg (claims 1 and 69) or 5-40mg (claim 59). The prior art of Wachtel et al. no longer anticipates claims 57, 61, 63 and 65 (which all depend from claim 57) as they teach a higher amount of lysine, however those claims are still rendered obvious by Wachtel et al. for the same reasons previously applied to claim 59 which was already claiming a lower amount than the prior art taught. These amounts however are well within the limits of routine optimization as discussed in the previous office action. It is noted by the examiner that the ratios claimed in claim 57 are still taught by Wachtel et al.

Applicant has traversed the previous obviousness rejection over claims 58-60, 62, 64 and 66-70, which now applies to all claims 57, 59, 61-70. Applicant argues that the present invention is not a refinement of the invention of Wachtel et al. because Wachtel et al. is concerned with improved treatment of PKU in juveniles and is not directed towards the specific problem that the present invention is intended to solve. Applicant is reminded that the claims are towards a *composition*, and therefore intended use carries no patentable weight if the prior art composition is capable of performing the use recited in the claims. It does not matter that applicant intends to use the composition in a slightly different way (both are intended to treat patients with PKU) and it doesn't matter if applicant did not develop their invention based on the teachings of Wachtel et al. There invention is still within the limits of routine optimization from the teachings of Wachtel et al. to find the optimum supplement formulation for each patient.

Applicant argues that Wachtel et al. provides a diet to replace the food that a patient with PKU would take and that the invention is a supplement designed to improve efficiency in the treatment of PKU patients. Applicant has not claimed their invention in any way that eliminates the diet of Wachtel et al., the word "supplement" is a broad term that is anything given to some to supplement a need for something, in this case essential amino acids. Applicant argues that Wachtel et al. does not disclose a supplement that would permit a patient to have an otherwise normal food intake, as discussed above the claims are not limited to such and they do not have to teach the intended use of the composition. The form it is delivered in, a pill versus food is not claimed by applicant and the claims would read upon a diet containing these ingredients so this argument is not found persuasive.

Applicant has argued that Wachtel et al. is not the closest prior art, that Pietz et al. should be considered more pertinent prior art. The examiner disagrees, despite the fact that Pietz teaches a supplement drawn to the same purpose as applicants, the composition itself is not closer than Wachtel et al. and the intended use does not carry patentable weight. Applicant has attempted to establish unexpected results by comparing their invention to Pietz et al. but it is not persuasive as applicant cannot choose what they deem to be the closest prior art, in order to establish unexpected results they must compare their invention to the closest prior art which is Wachtel et al. Further, even if Pietz et al. were the closest prior art applicant has not demonstrated unexpected results. Applicant indicated that information relating to Prekunil® was attached as Exhibit A but there is no attachment or exhibit A included in applicant's

response. Applicant points to table 6 (page 34 of specification) as evidence of unexpected results where Prekunil and their supplement SuppM1 are compared. It is noted that single mice were used for many of these groups (only the SuppM1 having 2 mice) and thus there is not way to tell if these results are statistically significant. Further, applicant indicates that the second to last group Prekunil + 100mg Leu as being the same thing as SuppM1, which is the group in the last column. These two groups are supposedly the same composition and yet have very different results. At 24 hours there is an average decrease of 19.5% in the Prekunil +100mg group, yet in the SuppM1 group (which is supposedly the same thing as both are indicated to be SuppM1) there is actually a 10 increase in the level. It points to an error or inconsistency amongst these results that the same composition would yield such drastically different results even if the numbers are similar at 6 hrs they were also very different at 3 hours (7% decrease to 20.5% decrease). It is also noted that at 6 hours the control group had a 13% decrease and at 24 hours it was 9.2% so there is obviously something happening to the levels in the mice independent of the supplement. This study does not demonstrate unexpected results or consistent results of any kind; towards either Pietz et al. or the closest prior art which is Wachtel et al.

Applicant's arguments have been fully and carefully considered however are not found to be persuasive. This rejection is a new rejection for claims 57, 61, 63 and 65 as they were anticipated in the prior rejection but the argument are the same as those previously applied for claims 58-60, 62, 64 and 66-70 which now apply to all claims 57, 59, 61-70.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/

Primary Examiner, Art Unit 1614